REMARKS

This is in response to the Official Action of December 5, 2001. The points raised therein are addressed below in the order originally set forth.

The action sets forth a restriction requirement between claims 1-2 and 4-12 as drawn to *in vivo* methods, and claims 1 and 3-7 and 9-12, as drawn to *ex vivo* methods. Claim 1 is acknowledged in the action to be a proper linking claim. Applicants affirm the election of the *ex vivo* group, without traverse. No claims are cancelled at this time pending resolution of the rejections of record. As noted below, applicant will amend claim 1 to recite *ex vivo* methods if such amendment will place this case in condition for allowance, but otherwise wishes to maintain claim 1 as currently pending in the event allowance of the *ex vivo* claims is not negotiated.

New claim 13, submitted to complete the record, is analogous to claim 1, except that it is directed to *ex vivo* treatment of the lung. New claim 13 is not duplicative of claim 3, in that a transplanting step is not required.

The specification is objected to in that "homologous" is misspelled on page 10, line 15. This spelling is corrected in the replacement paragraph submitted herein, and it is respectfully submitted that this rejection may be withdrawn.

Claims 1, 3-7 and 9-12 stand rejected as lacking description under the first paragraph of 35 USC 112. This rejection is respectfully traversed.

First, it is noted that originally presented claims are strongly presumed to satisfy the written description requirement. The written description requirement has recently evolved to require exemplification of multiple embodiments (*e.g.,* of a generic nucleic acid claim) where new compounds or compositions are claimed, but such is not the case here, as the instant invention is concerned with a new use of known materials (*see, e.g.,* the references associated with the Supplemental Information Disclosure Statement submitted concurrently herewith; references discussed in the "Background of the Invention" section of the instant application). Contrary to the argument presented in the Official Action, applicant is not attempting to preempt the future before it has arrived, but is attempting to patent a new use of a generic category of materials, numerous embodiments of which have already arrived. The patenting of new uses has long been considered appropriate subject matter for patenting, as exemplified by the numerous issued United States patents directed to such new uses.

The action cites *Pfaff v. Wells Electronics,* 48 USPQ2d 1641, 1646 (1998) where the Supreme Court established a "ready for patenting" standard in deciding that an "on sale" activity constituted a section 102(b) bar even though no actual or constructive reduction to practice had occurred. Although not a section 112 case, applicants agree that the general principles stated in *Pfaff* are applicable here, but point out that these principles encourage applicants to file early rather than late.

Claims 1, 3-7 and 9-12 stand rejected as lacking enablement under the first paragraph of 35 USC section 112. This rejection emphasizes the alleged lack of written description as set forth above, and hence is obviated for the reasons set forth in connection with the response to the written description rejection above. Further, in connection with both the written description and enablement rejections, it is noted that a patent specification "need not teach, and preferably omits, what is well known in the art" (MPEP section 2164.01).

In the Official Action, it is admitted that "the state of the art for lung transplantation has gained widespread acceptance as a therapeutic option for a diverse array of lung diseases". Problems with the technique are noted, but it is noted that most beneficial techniques have some risks and potential side effects. In the instant case, the state of the art is such that the USPTO can not properly shift the burden of establishing enablement to the applicant, and no reason to doubt the objective enablement provided by the specification is established (MPEP2164.04). Hence, it is respectfully submitted that this rejection should be withdrawn.

Claims 11-12, directed to "embryonic stem cells", has been cancelled to simplify the issues, such cells being generically encompassed by the claims of record.

Claims 1, 3-7 and 9-12 stand rejected as indefinite for various reasons, each of which is addressed below.

The phrase "in need thereof" with respect to lungs and recipients is objected to as indefinite. However, it is respectfully submitted that this phrase, or language substantially similar thereto, is well established language in numerous claims of issued United States patents, used simply to add context to the claims. Hence, reconsideration of this rejection is respectfully requested. If upon reconsideration the Examiner would simply prefer that the phrase "in need thereof" be stricken from the claims, the Examiner is authorized to do so by Examiner's amendment.

Claims 3-7 and 9-11 (and 12) have been amended to recite "The method" rather than "A method". Although the language "A method" has long been considered acceptable by the

USPTO and is found in numerous issued patents, this change is submitted to be only cosmetic in nature and applicants wish to comply with the current preferences of the USPTO.

Claims 4-6 have been amended to recite "lung" in the place of "subject" to provide proper antecedent basis.

Claim 6 has been amended to recite "stem" rather than "step" to provide proper antecedent basis.

The changes made by the amendments above are shown in the attached **"Version with Markings to Show Changes Made".**

It is respectfully submitted that this application is in condition for allowance, which action is respectfully requested.

Respectfully submitted,

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PATENT TRADEMARK OFFICE

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner For Patents, Washington, DC 20231, on June 5, 2002.

Vickie Diane Prior
Date of Signature: June 5, 2002

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Version with Markings to Show Changes Made

(amended) (4) Injection of the [hologous] homologous stem cells intraveneously or intra-arterially or trans-tracheally into the subject;

2 (amended). The [A] method according to claim 1, wherein said lung is *in vivo* in a subject in need of said treatment.

3 (amended). The [A] method according to claim 1, wherein said lung is *ex vivo*, and wherein said administering step is followed by the step of:

transplanting said lung into a recipient in need thereof.

4 (amended). The [A] method according to claim 1, wherein said [subject] lung is a mammalian [subject] lung.

5 (amended). The [A] method according to claim 1, wherein said [subject] lung is a human [subject] lung.

6 (amended). The [A] method according to claim 1, wherein said [step] stem or progenitor cells are from the same species as said [subject] lung.

7 (amended). The [A] method according to claim 1, wherein said progenitor cells are autologous cells.

8 (amended). The [A] method according to claim 1, wherein said administering step is carried out by intravenous injection, intra-arterial injection, or intra-bronchial administration.

9 (amended). The [A] method according to claim 1, wherein said stem or progenitor cells are lung cells.

10 (amended). The [A] method according to claim 1, wherein said stem or progenitor cells are bone marrow cells.

13 (new). An *ex vivo* method of stimulating the growth of lung alveolar surface in a lung in need thereof, comprising:

providing progenitor or stem cells capable of regenerating lung alveolar surface; and

administering said progenitor or stem cells to said lung *ex vivo* in an amount sufficient to stimulate the growth of lung alveolar surface therein.